



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: QIU, Bo *et al.*
APPLICATION No.: 09/982,259
FILED: October 17, 2001
FOR: BORELLIA BURGDOFFER EPI TOPE PEPTIDES

EXAMINER: RODNEY SWARTZ
ART UNIT: 1645

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is being deposited on August 25, 2004, with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.


AMY SHIELDS

INFORMATION DISCLOSURE STATEMENT AFTER THE MAILING OF A FIRST OFFICE ACTION – 37 C.F.R. § 1.97(c)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

1. Timing of Submission

The information transmitted herewith is being filed after the mailing of the first office action but before the mailing of a final office action or a notice of allowance. The references listed on the enclosed Form PTO-1449 (modified) may be material to the examination of this application; the Examiner is requested to make them of record in the application.

2. Cited Information

☒ Copies of the following references are enclosed:

- ☒ All cited references
- ☐ References marked by asterisks
- ☐ The following:

☐ Copies of the following references can be found in parent U.S. Application No. :

- ☐ All cited references
- ☐ References marked by asterisks
- ☐ The following:

- ☐ This application was filed after 30 June 2003 and no copies of U.S. patents nor published applications are enclosed (See Notice of Deputy Commissioner Kunin on 11 July 2003).
- ☐ The following references are not in English. For each such reference, the undersigned has enclosed (i) a translation of the reference; (ii) a copy of a communication from a foreign patent office or International Searching Authority citing the reference, (iii) a copy of a reference which appears to be an English-language counterpart, or (iv) an English-language abstract for the reference prepared by a third party. Applicant has not verified that the translation, English-language counterpart or third-party abstract is an accurate representation of the teachings of the non-English reference, though, and reserves the right to demonstrate otherwise.
- ☐ All cited references
☐ References marked by asterisks
☐ The following:

3. Effect of Information Disclosure Statement (37 C.F.R. § 1.97(h))

This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

4. Fee Payment (37 C.F.R. § 1.97(c)) or Certification (37 C.F.R. § 1.97(e))

- ☒ The required fee is \$180.00.
- ☒ Check enclosed for \$180.00.
☐ Please charge the above fee(s) to Deposit Account No. **50-2586** this paper is provided in triplicate.
- ☐ Applicant submits that no fee is due in light of the following certification under 37 C.F.R. § 1.97(e) (check only one):
- ☐ In accordance with 37 C.F.R. § 1.97(e)(1), the undersigned hereby states that each item of information submitted herewith was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to this filing of this statement; or
- ☐ In accordance with 37 C.F.R. § 1.97(e)(2), the undersigned hereby states that no item of information submitted herewith was cited in a

communication from a foreign patent office in a counterpart foreign application, or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c), more than three months prior to the filing of this statement.

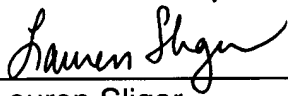
- ☒ Please charge any underpayment for timely filing of this paper to Deposit Account No. **50-2586**.

5. Patent Term Adjustment (37 C.F.R. § 1.704(d))

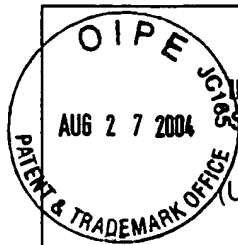
- ☐ The undersigned states that each item of information submitted herewith was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this statement. 37 C.F.R. § 1.704(d).

Respectfully submitted,
Perkins Coie LLP

Dated: August 25, 2004

By: 
Lauren Sliger
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
Form PTO-1449 (Modified)
(Use several sheets if necessary)

COMPLETE IF KNOWN

Application Number	09/982,259
Confirmation Number	8229
Filing Date	October 17, 2001
First Named Inventor	Bo Qiu
Group Art Unit	1645
Examiner Name	Rodney Swartz
Attorney Docket No.	54114.8002.US00

Sheet 1 of 4

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	U.S. Patent or Application		Name of Patentee or Inventor of Cited Document	Date of Publication or Filing Date of Cited Document	Pages, Columns, Lines, Where Relevant Figures Appear
		NUMBER	Kind Code (if known)			
	C14	4,970,300		Fulton	11/1990	
	C15	5,187,065		Schutzer	02/16/1993	
	C16	5,219,564		Zalipsky	06/15/1993	
	C17	5,455,027		Zalipsky	10/03/1995	
	C18	5,545,698		Barany	08/13/1996	

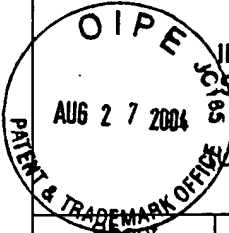
FOREIGN PATENT DOCUMENTS

Exami ner Initial	Cite No.	Foreign Patent or Application			Name of Patentee or Applicant of Cited Document	Date of Publication or Filing Date of Cited Document	Pages, Columns, Lines, Where Relevant Figures Appear	T
		Office	NUMBER	Kind Code (if known)				
	C19	WO	91 13630		United States of America	09/19/1991		
	C20	WO	97 42221		Statens Seruminstitut	11/13/1997		

OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS

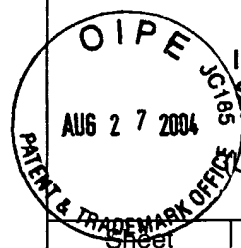
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published.	T
	C21	BARBOUR, "The Biological and Social Phenomenon of Lyme Disease", 260 Science 1610 (1993).	
	C22	BRUNNER, "Immune Complexes from Serum of Patients with Lyme Disease Contain Borrelia burgdorferi Antigen and Antigen-Specific Antibodies: Potential Use for Improved Testing", 182 J. of Infectious Diseases 534 (2000).	
	C23	BRUNNER, "Immunoglobulin M Capture Assay for Serologic Confirmation of Early Lyme Disease: Analysis of Immune Complexes with Biotinylated Borrelia burgdorferi Sonicate Enhanced with Flagellin Peptide Epitope", 36 J. Clin. Micro. 1074 (1998).	
	C24	BRUNNER, "New Method for Detection of Borrelia burgdorferi Antigen Complexed to Antibody in Seronegative Lyme Disease", 249 J. Immunol. Methods 185 (2001).	

EXAMINER	DATE CONSIDERED
<p>*EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance <u>and</u> not considered. Include copy of this form with next communication to application(s).</p>	

 INFORMATION DISCLOSURE STATEMENT BY APPLICANT Form PTO-1449 (Modified) Use several sheets if necessary				COMPLETE IF KNOWN	
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				Examiner Name	Rodney Swartz
Sheet	2	of	3	Attorney Docket No.	54114.8002.US00

OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published.	T
	C26	BÜCKMANN, "Functionalization of Poly(ethylene glycol) and Monomethoxy-Poly(ethylene glycol)", 182 Makromol Chem. 1379 (1981).	
	C27	ERVIN, "The Bell Tolls for the Infectious Diseases Clinician", 153 J Inf Dis 183 (1986).	
	C28	FRANK, "Spot Synthesis: An Easy Technique for the Positionally Addressable, Parellel Chemical Synthesis on a Membrane Support", 48 Tetrahedron 9217 (1992).	
	C29	GECKELER, "Functionalization of Soluble Polymers", 1 Polym. Bull 427 (1979).	
	C30	GEYSEN, "Use of Peptide Synthesis to Probe Viral Antigens for Epitopes to a Resolution of a Single Amino Acid", 81 Proc. Natl. Acad. Sci. 3998 (1984).	
	C31	GILMORE, "Outer Surface Protein C (OspC), but not p39, is a Protective Immunogen Against a Tick-Transmitted Borrelia burgdorferi Challenge: Evidence for a Conformational Protective Epitope in OspC", 64 Infection and Immunity 2234 (1996).	
	C32	JUNGBLUT, "Proteomics in Human Disease: Cancer, Heart and Infectious Diseases", 20 Electrophoresis 2100 (1999).	
	C33	MAGNARELLI, "Cross Reactivity of Nonspecific Treponemal Antibody in Serologic Tests for Lyme Disease", 28 J. Clin. Microbiol. 1276 (1990).	
	C34	MATHIESEN, "The Dominant Epitope of Borrelia garinii Outer Surface Protein C Recognized by Sera from Patients with Neuroborreliosis Has a Surface-Exposed Conserved Structural Motif", 66 Inf. And Immun. 4073 (1998).	
	C35	MATHIESEN, "Peptide Based OspC Enzyme-Linked Immunosorbent Assay for Serodiagnosis of Lyme Borreliosis", 36 J. Clin. Microbiol. 3474 (1998).	
	C36	QIU, "Studies on Polymers for Biomedical Applications:...", (Dissertation, Oct. 1999) (unpublished).	
	C37	SCHNEIDER, "Prognostic B-Cell Epitopes on the Flagellar Protein of Borrelia burgdorferi", 60 Inf and Immun. 316 (1992).	
	C38	SIGAL, "The Lyme Disease Controversy", 156 Arch. Intern. Med 1493 (1996).	

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Sheet 3 of 3

OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS

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	C39	SIGAL, "Pitfalls in the Diagnosis and Management of Lyme Disease", 41 Arthritis & Rheumatism 195 (1998).	
	C40	SIGAL, "The Polymerase Chain Reaction Assay for Borrelia burgdorferi in the Diagnosis of Lyme Disease", 120 Annals Intern. Med. 520 (1994).	
	C41	SIGAL, "A Vaccine Consisting of Recombinant Borrelia burgdorferi Outer-Surface Protein A to Prevent Lyme Disease", 339 New Engl. J. Med. 216 (1998).	
	C42	SIMPSON, "Antibody to a 39-Kilodalton Borrelia burgdorferi Antigen (P39) as a Marker for Infection in Experimentally and Naturally Inoculated Animals", 29 J. Clin Microbiol 236 (1991).	
	C43	SIMPSON, "Nucleotide Sequence and Analysis of the Gene in Borrelia burgdorferi Encoding the Immunogenic P39 Antigen", 119 Fed of Europ. Microbiol. Soc.s Letters 381 (1994).	
	C44	SIMPSON, "Reactivity of Human Lyme Borreliosis Sera with a 39-Kilodalton Antigen Specific to Borrelia burgdorferi", 28 J. Clin Microbiol 1329 (1990).	
	C45	YU, "Multi-Well ELISA Based on Independent Peptide Antigens for Antibody Capture", 198 J. Immunol. Meth. 25 (1996).	
	C46	YU, "Presentation of Peptide Antigens as Albumin Conjugates for Use in Detection of Serum Antibodies by Enzyme-Linked Immunosorbent Assay", 7 Bioconjugate Chem. 338 (1996).	
	C47	ZALIPSKY, "Attachment of Drugs to Polyethylene Glycols", 19 Eur. Polym. J. 1177 (1983).	
	C48	ZALIPSKY, "Esterification of Polyethylene Glycols", A21 J Macromol. Sci.-Chem. 839 (1984).	
	C49	ZALIPSKY, "Functionalized Poly(ethylene glycol) for Preparation of Biologically Relevant Conjugates", 6 Bioconjugate Chem. 150 (1995).	

EXAMINER

DATE CONSIDERED

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1645

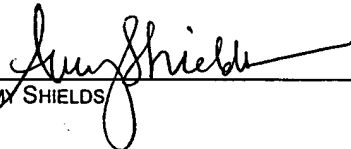
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: QIU, *et al.*
APPLICATION No.: 09/982,259
FILED: OCTOBER 17, 2001
FOR: BORELLIA BURGENDORFERI EPITOPE
PEPTIDES

EXAMINER: RODNEY SWARTZ
ART UNIT: 1645

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is being deposited this day, August 25, 2004, with the United States Postal Service as first class mail in an envelope addressed to U.S. Patent and Trademark Office, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.


AMY SHIELDS

Transmittal of Information Disclosure Statement and Substitute Sequence Listing

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

1. Transmitted herewith are the following:

- ☐ Amendment and Response to Office Action
- ☐ Petition for Extension of Time
- ☐ Terminal Disclaimer
- ☒ Sequence Listing printout, floppy diskette, matching statement
- ☒ Information Disclosure Statement, Form PTO-1449 (modified), References.
- ☒ Check in the amount of \$180.00.

2. Explanation of Substitute Sequence Listing

A new sequence listing is enclosed, correcting the organism type for all sequences from Homo sapiens to Borrelia burgdorferi.

3. Conditional Petition for Extension of Time:

Applicant petitions for an Extension of Time, if necessary, for timely of this transmittal and enclosures.

08/30/2004 JBALINAH 00000042 09982259

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180.00 DP

4. Fee Calculation and Payment

For:	(Col. 1) No. Filed	(Col. 2) No. Extra	Small Entity			Other Than a Small Entity	
			Rate	Fee	Rate	Fee	
Total Claims			x \$ 9 =	\$	or	x \$ 18 =	\$
Independent Claims			x \$43 =	\$	or	x \$ 86 =	\$
<input type="checkbox"/> Multiple Dependent Claim Presented			+ \$140 =	\$	or	+ \$280 =	\$
<input type="checkbox"/> Extensionfee				\$			
<input checked="" type="checkbox"/> Information Disclosure Statement Fee				\$180.00			
*If the difference in Col. 1 is less than zero, enter "0" in Col. 2.			TOTAL	\$180.00	or	TOTAL	

A check in the amount of \$180.00 is enclosed.

5. Provisional Fee Authorization

Please charge any underpayment in fees for timely filing of this transmittal and enclosures or credit any overpayment of fees to Deposit Account No. 50-2586.

Respectfully submitted,
Perkins Coie LLP

Date: August 25, 2004


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Registration No. 51,086

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